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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,305	12/06/2001	Charles E. Prussak	041673-2092	1335

30542 7590 08/01/2006

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EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/006,305	PRUSSAK ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-4,8,11,12,14,16-21,23-29,32-41,43-51 and 62-75* is/are pending in the application.

4a) Of the above claim(s) *14,16-21,23-26,43-51 and 62-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-4,8,11,12,27-29,32-41 and 68-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 5/18/06, has been entered.
Claims 1, 5-7, 9-10, 13, 15, 22, 30-31, 42, 52-61 have been canceled.
Claims 68-75 have been added.

Claims 2-4, 8, 11-12, 14, 16-21, 23-29, 32-41, 43-51 and 62-75 are pending.

Applicant's election without traverse of Group I for examination, and the species wherein Domains I, II and III are fragments of CD154 (i.e. CD40L), while Domain IV comprised a fragment of human TNFα is acknowledged.

For examination purposes, the elected claims 2-4, 8, 11-12, 27-29, 32-41 and 68-75 are being examined to the extent they read on the elected species wherein Domains I, II and III are fragments of CD154 (i.e. CD40L), while Domain IV comprised a fragment of human TNFα.

Claims 14, 16-21, 23-26, 43-51 and 62-67 have been withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to the nonelected inventions and/or species.

2. With respect to the Information Disclosure Statement and the references provided 11/10/03; it is noted that the reference WO 98/26061 was provided but was not indicated on the corresponding 1449 that came in at the same time.

In the interest of compact prosecution and convenience, the examiner has indicated the reference WO 98/26061 on an PTOL-892, but has not provided the reference to applicant, as applicant has already provided this reference.

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention.

Applicant should avoid the use of novel in the title, as patents are presumed to be novel and unobvious.

4. The Abstract of the Disclosure is objected to because it does not adequately describe the claimed invention. Correction is required. See MPEP 608.01(b).

5. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected

Trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required

6. In the interest of clarity, applicant is invited to consider amending the claims to "TNFα protein" to simply "TNFα", as "TNFα" is the name of the protein.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 14, 16-21, 23-26, 43-51 and 62-67 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kipps et al. (U.S. Patent No. 7,070,771) AND/OR Kipps et al. (WO 98/26061) (provided by applicant on 11/10/03, but not cited on the corresponding 1449) in view of Mueller et al. (J. Biol. Chem.274: 1999) (1449).

Both Kipps et al. (U.S. Patent No. 7,070,771 and WO 98/26061) (see entire documents) teach chimeric molecules, including nucleic acids encoding accessory molecules ligands (and associated vectors, including viral vectors and regulatory regions host cells such as tumor cells and antigen presenting cells and methods of producing the chimeric molecules) which are made up of various domains and sub-domains of molecules derived from the tumor necrosis factor molecules, which, in turn, contain unique properties which lead to the stabilization of their activities and greater usefulness in the treatment of diseases (see entire document, including Abstracts and Summary of the Inventions). The Detailed Description of the Invention these prior art references describe the very CD154 / CD40L domain structures to be utilized as well as TNFα itself as well as the Domain Structure of Tumor Necrosis Factor Family Molecules (e.g. see Table 1 on column 15 of U.S. Patent No. 7,070,771 and page 29 of WO 98/26061).

While the prior art Kipps et al. references contemplate chimeric accessory molecules comprising any domain, sub-domain and portions of the disclosed molecules, including CD154/CD40L and TNFα (e.g., see Detailed Description of the Inventions), these references do not set out the particular nucleic acid molecules comprising a Domain IV fragment of TNFα and the rest of the molecule comprising CD40L per se.

These Kipps et al. references do note that the fourth domain (Domain IV) of the accessory molecule ligand gene(s) is called the distal extracellular domain and that the secondary structures of the accessory molecule(s) were deduced based upon CD40L and human TNF (e.g. see column 14-15, overlapping paragraph of U.S. Patent No. 7,070,771 and pages 27-28 of WO 98/26061).

Mueller et al. teach the advantages and, in turn, constructs comprising transmembrane TNFα, which include deleting proteolytic cleavage sites of TNFα to prevent the deleterious effects of cleaved TNFα (see entire document, including Abstract, Introduction and Discussion). Mueller et al. also discusses the role of TNFα in association with CD154 / CD40L as well as the use of transmembrane TNFα therapeutically (see Discussion, including page 38117, columns 1-2).

Therefore, it would have been prima obvious to the ordinary artisan at the time the invention was made to construct nucleic acids encoding chimeric accessory molecules, including the construction of TNFα on the extracellular domain with domains of CD154 / CD40L in order to take advantage of of the known uses of TNFα, but to avoid the deleterious effects of some or pleiotropic properties of TNFα, such as endotoxic shock, as taught by both Kipps et al. references and Mueller et al. Both Kipps et al. references clearly teach mixing and matching members of the TNF family and rely upon the predicted structures of TNFα and CD154/CD40L per se as a basis for their teachings of constructing chimeric accessory molecules. Nucleic acids comprising SEQ ID NO: 1 would have been an expected or intrinsic property of chimeric molecules comprising human TNFα linked to CD154/CD40L Domains I, II and III.

One of ordinary skill in the art at the time the invention was made would have been motivated to select an extracellular domain of TNFα with CD154/CD40L domains to achieve the use of TNFα and to avoid the deleterious effects of TNFα by construcing chimeric accessory molecules which contain unique properties which lead to the stabilization of their activities and greater usefulness in the treatment of diseases, as taught by the Kipps et al. references.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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July 24, 2006

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